REMARKS

Upon entry of the present amendment, claims 12, 27, 28, 30, and 33-37 are pending in the application. Claim 32 has been canceled, and claims 33-36 have been amended herein. Support for these amendments can be found in the originally filed application. No new matter has been added.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 34-37 were rejected under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner indicates that claims 34 and 36 depend from canceled claims 26, 29 and 31. Applicants have amended claims 34 and 36 herein to depend from pending claims 12, 27-28, 30 and 33. The Examiner also indicates that claim 35 is indefinite in the recitation of the phrase, "or claim 34." Applicants have amended claim 35 herein to replace the "or" with "of" as suggested by the Examiner. These rejections have been overcome and should be withdrawn.

Rejections under 35 U.S.C. § 101 for non-statutory subject matter

Claim 35 was rejected under 35 U.S.C. § 101 as containing non-statutory subject matter. Applicants have amended claim 35 herein to specify, "[a]n **isolated** host cell." (Emphasis added.) Applicants assert that amended claim 35 is directed to statutory subject matter and request withdrawal of this rejection.

Rejections under 35 U.S.C. § 102

A. Ford

Claims 32-37 were rejected under 35 U.S.C. § 102(e), as being anticipated by Ford (US Patent 6,294,655; "Ford"). Claim 32 has been canceled herein. Thus, this rejection is moot in regard to claim 32. According to the Examiner, the complement of the nucleic acid of Ford would be expected to hybridize to SEQ ID NO: 1 under the moderate hybridization conditions recited in the claims and also meets the "300 consecutive nucleotides of SEQ ID NO: 1, 1-600" limitation. (See, Office action at pages 2, 3, 9 and 10). In applying SEQ ID NO:6 of Ford, the Examiner states that the subject matter of pending claims is not entitled to the claimed priority

date of July 16, 1999 (the filing date of US provisional application 60/442,298 ("the '298 application") because while the claimed nucleic acid is disclosed in the '298 provisional application, the parent application does not provide a specific and substantial asserted utility or a well established utility for the claimed invention. (See, office action, pages 6-7.) However, as discussed below, Applicants have demonstrated that the parent application and the pending application adequately provide a specific and substantial asserted utility or a well established utility for the claimed invention. Therefore, Applicants assert that the pending claims are entitled to a priority date of at least July 16, 1999, the filing date of the '298 provisional application.

Claim 33 has been amended herein to delete section (b), which relates to hybridization conditions. Claims 34 and 36 have been amended herein to delete the reference to canceled claim 32. Amended claim 33 does not recite hybridization conditions. Moreover, amended claim 33 requires a nucleic acid molecule comprising nucleotides 1-600 of SEQ ID NO:1. Applicants assert that Ford does not teach a nucleic acid molecule comprising nucleotides 1-600 of SEQ ID NO:1, as the nucleic acid of SEQ ID NO: 6 disclosed by Ford contains a gap at position 507 of SEQ ID NO: 1 of the present application. Thus, Ford does not anticipate amended claim 33. Claims 34-37 depend from claim 33 and necessarily contain all the limitations thereof. Therefore, as claim 33 is not anticipated by Ford, Applicants assert that the dependent claims also are not anticipated by this reference. Applicants request that this rejection be withdrawn.

B. Jeffreys *et al.*

Claim 32 was rejected under 35 U.S.C. § 102(b), as being anticipated by Jeffreys *et al.* (Accession Number AAQ95200; "Jeffreys"). Claim 32 has been canceled herein. Thus, this rejection is moot and should be withdrawn.

C. Stausberg *et al.*

Claim 32 was rejected under 35 U.S.C. § 102(b), as being anticipated by Stausberg *et al.* (Accession Number AI252833; "Stausberg"). Claim 32 has been canceled herein. Thus, this rejection is moot and should be withdrawn.

D. Mulero *et al.*

Claims 32 and 33 were rejected under 35 U.S.C. § 102(a), as being anticipated by Mulero *et al.* (Accession Number AF186094, dated October 16, 1999; "Mulero"). Claim 32

has been canceled herein. Thus, this rejection is moot in regard to claim 32. Claim 33 has been amended herein to delete section (b). Applicants traverse this rejection to the extent that it applies to amended claim 33.

According to the Examiner, Mulero teaches an isolated nucleotide which is 97.1% homologous to SEQ ID NO: 1 and comprises over 500 consecutive nucleotides of SEQ ID NO: 1. The Examiner has applied Mulero based on the rejection of the priority claim to the '298 application. However, as discussed herein, Applicants have demonstrated that the parent application and the pending application adequately provide a specific and substantial asserted utility or a well established utility for the claimed invention. Therefore, Applicants assert that pending claim 33 is entitled to a priority date of at least July 16, 1999, the priority date of the '298 provisional application. Thus, Mulero is not available as prior art under 35 U.S.C. § 102(b) in regard to claim 33. Moreover, amended claim 33 requires a nucleic acid molecule comprising nucleotides 1-600 of SEQ ID NO:1. Applicants assert that Mulero does not teach a nucleic acid molecule comprising nucleotides 1-600 of SEQ ID NO:1, as the nucleic acid disclosed by Mulero contains a gap at position 507 of SEQ ID NO: 1 of the present application. Thus, Mulero does not anticipate amended claim 33. For these reasons, claim 33 is not anticipated by this reference, and this rejection should be withdrawn.

Rejections under 35 U.S.C. § 101

Claims 12, 27-28, 30 and 32 -37 have been rejected under 35 U.S.C. § 101 for lack of utility. Claim 32 has been canceled herein. Thus, this rejection is moot in regard to claim 32. The Examiner has asserted that "[t]he instant specification lists a page of disparate diseases or disorders (neurological disorders, cancers, vascular disease, cardiac disorders, psoriasis, and alopecia areata etc.) that might be treatable or diagnosable under the claimed invention" but that "the specification never established a nexus between any of the listed disease and the polypeptide or nucleic acid of the instant invention." (*See* Office Action, page 5). Applicants traverse.

Applicants respectfully assert that the nucleic acids of the present invention have a specific, substantial, and credible utility, and therefore are patentable under 35 U.S.C. §101, based on the disclosure of the specification and the knowledge of one of ordinary skill in the art when the application was filed. As disclosed in the specification, the nucleic acids of the present invention are useful in diagnostic assays to diagnose or confirm that a symptomatic subject has a

genetic defect in an IL-1L1 gene that causes or contributes to an inflammatory disease or disorder, particularly when the genetic defect is a single nucleotide polymorphism (SNP). (See, the specification at *e.g.*, page 9, lines 8-22; also the '298 provisional application at, *e.g.*, page 86, lines 9-28.) The specification also discloses that information obtained by the diagnostic assays is also useful prognostically to predict whether a non-symptomatic subject is likely to develop an IL-1L1-related disease. (See the specification at, *e.g.*, page 9, lines 13-22.) The specification further describes a number of inflammatory diseases or disorders associated with aberrant IL-1L1 activity, including arthritis. (See the specification at, *e.g.*, page 87, lines 4-27; also the '298 provisional application at, *e.g.*, page 84, line 29 to page 85, line 22.) It has been subsequently determined by others in the field that specific SNP mutations in the IL-1L1 nucleic acid are associated with one form or arthritis, ankylosing spondylitis (AS). (See, *e.g.*, Timms *et al.*, Am. J. Hum. Genet. 75:587-95 (2004) ("Timms") (Exhibit A), wherein IL-1L1 is referred to as IL-1F5; courtesy copy provided herewith). As stated previously, IL-1L1 is also known as IL-1F5 (See, *e.g.*, Swiss-Prot accession number Q9UBH0.) Timms discloses several SNPs in the IL-1L1 gene and the significant association of IL-1L1 SNPs with AS. (See, *e.g.*, Timms, pages 588 and 590.) Applicants assert that this data should be considered when determining the specific, substantial, and credible utility of the present invention because of the clear nexus between the specification, which describes the diagnostic use of genetic defects, including SNPs, which cause or contribute to an inflammatory disease or disorder, such as arthritis, and the post-filing data of Timms. Therefore, Applicants assert that the present invention has a specific, substantial, and credible utility in the diagnosis of diseases or disorders, including AS, and as prognostic tools to determine whether a non-symptomatic subject is likely to develop an IL-1L1-related inflammatory disease. Applicants request withdrawal of this rejection.

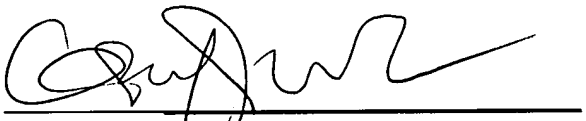
Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 12, 27-28, 30 and 32 -37 under 35 U.S.C. § 112, first paragraph, for not being supported by either a specific or substantial asserted utility. Claim 32 has been canceled herein. Thus, this rejection is moot in regard to claim 32. Applicants have demonstrated above, that claims 12, 27-29, 30, and 33-37 are supported by such a utility. Therefore, this rejection should be withdrawn.

CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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